UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CYNTHIA DIBARTOLO,

Plaintiff,

- against -

ABBOTT LABORATORIES,

Defendant.

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MEMORANDUM AND ORDER

12 Civ. 900 (NRB)

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

I. Introduction

Plaintiff Cynthia DiBartolo ("DiBartolo" or "plaintiff") brings this action against defendant Abbott Laboratories ("Abbott" or "defendant") to recover for injuries she allegedly suffered as a result of her use of defendant's drug Humira to treat psoriasis. After treatment with Humira for approximately six months, Am. Compl. ¶ 56, plaintiff was diagnosed with non-melanoma skin cancer (NMSC), specifically squamous cell carcinoma of the tongue, id. ¶¶ 33, 60, and underwent two surgeries that have allegedly left her with permanent disabilities, id. ¶¶ 65-69. In her First Amended Complaint (the "amended complaint"), filed on May 8, 2012, plaintiff asserted causes of action sounding in strict liability, negligence, and breach of warranty based on theories of design defect, failure to warn, and misrepresentation. Id. ¶¶ 78-80. Defendant filed

a motion to dismiss plaintiff's amended complaint on May 25, 2012. Plaintiff filed her response to defendant's motion to dismiss on June 15, 2012, and defendant filed its reply in support of its motion to dismiss plaintiff's amended complaint on June 29, 2012. For the reasons stated below, defendant's motion to dismiss is granted in part and denied in part.

II. Background

A. Plaintiff's Pre-Treatment History

According to the amended complaint, DiBartolo, aged 49 as of the date the amended complaint was filed, is an attorney residing in New York City who has struggled with psoriasis periodically throughout her life. Am. Compl. ¶¶ 54-55, 69. Prior to her use of Humira, DiBartolo underwent various treatment regimes for her psoriasis, notably including PUVA therapy.[1] Id. ¶ 55.

In late 2008, DiBartolo's psoriasis symptoms worsened, possibly related to an increase in stress, and on or about November 5, 2008, DiBartolo sought treatment for the first time from Dr. James Cui, a dermatologist in New York City. Id. ¶ 56.

[1] Plaintiff explains in her amended complaint that "PUVA" is an acronym that results from the combination of "psoralen" and "UVA." In PUVA therapy, the patient takes the medication psolaren, which makes the skin more sensitive to UVA light, before entering a UVA light box. This treatment can be very effective for clearing psoriasis. PUVA therapy is also known as "photochemotherapy." Am. Compl. ¶ 55 n.17; see also Am. Acad. of Dermatology, PUVA Therapy for Psoriasis, http://www.skincarephysicians.com/psoriasisnet/PUVA_therapy.html (last visited Dec. 20, 2012).

During that visit, Dr. Cui prescribed DiBartolo Humira in a dose of 40 mg every other week. Id.

B. Humira

Humira is a drug manufactured by Abbott that was initially launched in 2003 to treat rheumatoid arthritis. Am. Compl. ¶ 8; see also Letter from Jay P. Siegel, Food and Drug Admin. ("FDA"), to Jeanne Fox, Abbott Labs. (Dec. 31, 2002), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/adalabb123102L.htm (approving Humira, whose generic name is "Adalimumab," for treatment only of rheumatoid arthritis). As explained in the amended complaint, Humira belongs to a class of drugs known as "TNF-alpha blockers." Am. Compl. ¶ 5. These drugs operate by blocking the negative effects of Tumor Necrosis Factor (TNF), a protein that is naturally produced as part of the body's immune system but which reaches excess levels in persons with certain diseases, including plaque psoriasis. See Humira Medication Guide, attached to Humira Label, Feb. 2008, at 34, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/125057s114lbl.pdf [hereinafter Humira Label]. Humira is administered by subcutaneous injection, performed either by medical professionals or by patients themselves. Humira Label, at 1, 4-5.

Subsequent to Humira's 2003 launch, Abbott obtained the FDA's approval of several other indications for the drug. See

Am. Compl. ¶ 8. In January 2008, the FDA approved Abbott's application for a Humira indication for "the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate." Letter from Susan J. Walker, FDA, to Meg Drew, Abbott Labs. (Jan. 18, 2008), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/125057s0110ltr.pdf [hereinafter Letter from FDA to Abbott (Jan. 18, 2008)]; see also Am. Compl. ¶ 26; Humira Label, Jan. 2008, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/125057s0110lbl.pdf. This is the indication under which Dr. Cui prescribed Humira to DiBartolo. See Am. Compl. ¶¶ 55-56.

As it would be required to do for any prescription drug, Abbott prepared a detailed label for Humira, which was approved by the FDA and which Abbott distributed to physicians to inform them about how Humira should be used and what risks were associated with its use.[2] Humira Label, Jan. 2008, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/125057s0110lbl.pdf; 21 C.F.R. pt. 201 (2012). According to the Humira label in place throughout the course of DiBartolo's Humira treatment, patients taking Humira are at risk for a number of

[2] These warnings are also known as "package inserts" or "professional labeling." See 21 CFR § 601.14(b) (2012).

serious side effects. In particular, the label warned on the first page that "[m]alignancies [] are seen more often than in controls." Humira Label, at 1. In the "Warnings and Precautions" section for "Malignancies," the label elaborated:

> In the controlled portions of clinical trials of some TNF-blocking agents, including HUMIRA, more cases of malignancies have been observed among patients receiving those TNF blockers compared to control patients. . . . During the controlled portions of HUMIRA rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, and plaque psoriasis trials, the rate (95% confidence interval) of non-melanoma (basal cell and squamous cell) skin cancers was 0.9 (0.57, 1.35)/100 patient-years among HUMIRA-treated patients and 0.3 (0.08, 0.80)/100 patient-years among control patients. The potential role of TNF blocking therapy in the development of malignancies is not known.

Id. at 6-7. In the "Warnings and Precautions" section for "Immunosuppression," the label warned:

> The possibility exists for TNF blocking agents, including HUMIRA, to affect host defenses against infections and malignancies since TNF mediates inflammation and modulates cellular immune responses. . . . The impact of treatment with HUMIRA on the development and course of malignancies, as well as active and/or chronic infections, is not fully understood . . . .

Id. at 9. In the "Adverse Reactions" section, the label warned that "[t]he most serious adverse reactions" were serious infections, neurologic reactions, and malignancies. Id. With regard to malignancies, the label explained: "More cases of malignancy have been observed in HUMIRA-treated patients compared to control-treated patients in clinical trials . . . ."

Id. at 10. With regard to "[o]ther [a]dverse [r]eactions," the label warned: "Other infrequent serious adverse reactions occurring at an incidence of less than 5% in rheumatoid arthritis patients treated with HUMIRA were: . . . Neoplasia: Adenoma, carcinomas such as breast, gastrointestinal, skin, urogenital, and others; lymphoma and melanoma." Id. at 12-13. Given these significant risks associated with Humira, the label stated in the "Indications and Usage" section that "HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician." Id. at 3-4.

When the FDA approved Humira for treatment of plaque psoriasis in January 2008, it determined that the "serious and significant public health concern relating to increased risk for serious infections" posed by Humira justified a requirement, under 21 CFR § 208, that Abbott publish a Medication Guide to inform patients directly of Humira's risks. Letter from FDA to Abbott (Jan. 18, 2008), at 4. The Medication Guide distributed while DiBartolo used Humira warned patients that "[s]erious side effects, which sometimes lead to death, have happened in patients taking HUMIRA," including "[s]erious infections" and "[c]ertain types of [c]ancer." Humira Medication Guide, attached to Humira Label, at 36. In particular, the Medication Guide warned:

> There have been cases of certain kinds of cancer, in patients taking HUMIRA or other TNF blockers. Some patients receiving HUMIRA have developed types of cancer called nonmelanoma skin cancer (basal cell cancer and squamous cell cancer of the skin), which are generally not life-threatening if treated. Tell your doctor if you have a bump or open sore that doesn't heal.

Id. The Medication Guide also warned that Humira patients were at risk of nervous system problems, the signs and symptoms of which could include "numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness." Id. at 37. The Medication Guide was reprinted at the end of the Humira label, so any warnings contained in the Medication Guide were transmitted to both patients and physicians. See Humira Label, at 33-43; see also 21 CFR § 201.57(c)(18).

C. Plaintiff's Treatment and Alleged Harm

After being prescribed Humira on November 5, 2008, DiBartolo took injections every two weeks for approximately six months. Am. Compl. ¶ 56. According to the amended complaint, DiBartolo was never screened for NMSC by Dr. Cui, was never warned that she was at a higher risk of developing NMSC because of her history of PUVA treatment, and was not monitored for the development of NMSC during the time she took Humira. Id. Indeed, DiBartolo never saw Dr. Cui after the initial visit in which he prescribed her Humira. Id. ¶ 28 n.12.

On April 16, 2009, DiBartolo visited her dentist, Dr. John Purpura, with regard to a bonded tooth. Id. ¶ 58. During his examination of DiBartolo, Dr. Purpura "noticed a raised, velvety, irregular white mass on the left side of [DiBartolo's] tongue and advised [DiBartolo] to have it biopsied immediately." Id. DiBartolo accordingly arranged for a biopsy of the mass on her tongue and discontinued her injections of Humira. Id.

Four days later, DiBartolo underwent a surgical biopsy as well as a flexible laryngoscopy, wherein a doctor examined her voice box and throat by passing an endoscope through her nose and throat. Id. ¶ 59. Two days after the biopsy and laryngoscopy, Dr. David Kutler, an otolaryngologist with New York Presbyterian Hospital, diagnosed DiBartolo with Malignant Neoplasm of the Tongue - Squamous Cell Carcinoma. Id. ¶ 60. Dr. Kutler recommended that DiBartolo undergo surgery and further treatment for the cancer. Id.

After opting not to undergo a "mandibulotomy," a surgical procedure that several doctors recommended but that "leaves the patient disfigured and with limited opportunities for functionality," id. ¶ 61, DiBartolo agreed to undergo a less disfiguring procedure to be performed by Drs. Daniel Buchbinder and Mark Urken, id. ¶ 62. Prior to surgery, DiBartolo got her personal affairs in order and formally consented to a

mandibulotomy under sedation if her doctors determined that it was absolutely necessary. Id. ¶¶ 63-64.

The surgery was performed on May 18, 2009, at Beth Israel Medical Center Head and Neck Cancer Institute. Id. ¶ 62. Luckily for DiBartolo, the surgery proceeded successfully as planned, without need to resort to a mandibulotomy. Id. ¶ 65. In a day-long procedure, the surgeons conducted a partial glossectomy, removing a substantial portion of DiBartolo's tongue, performed a radical neck dissection to remove all lymph nodes and tissue that were likely malignant, and reconstructed DiBartolo's tongue through microsurgical free flap surgery. Id. DiBartolo remained in the hospital for eight days following surgery, undergoing three blood transfusions and experiencing serious respiratory complications, but was discharged on May 28, 2009, after stabilizing and regaining the ability to breathe independently. Id. ¶ 66.

After her discharge, DiBartolo commenced daily speech therapy at Beth Israel Medical Center with Jacqueline Mojica and Dr. John Haskell, as well as treatment for depression by Dr. Israel Klein. Id. On November 1, 2010, DiBartolo underwent another surgical procedure at Beth Israel Medical Center to remove a non-malignant neuroma on the left side of her tongue. Id. ¶ 67. In March 2011, DiBartolo began neurologic testing in

response to "seizure-like episodes" that she experiences up to five times a day. Id. ¶ 68.

According to the amended complaint, DiBartolo's cancer is in remission, though DiBartolo will need to undergo periodic PET/CT scans until the fifth anniversary of her surgery to monitor for any reoccurrence of the cancer. Id. ¶ 69. DiBartolo's speech has improved somewhat, but remains sufficiently impaired that DiBartolo receives long-term disability benefits. Id. ¶¶ 66-69. DiBartolo additionally alleges that she continues to experience weakness on her left side, chronic pain, difficulty eating and swallowing, periodic dysphagia, limited range of motion in her left hand and arm, impaired hearing in her left ear, scarring in numerous areas, and permanent impairment of her lymphatic system on the left side, such that she must regularly perform manual lymphatic drainage to remove accumulated fluids. Id.

III. Discussion

A. Jurisdiction

The Court has jurisdiction over the subject matter of this case based on diversity of citizenship. See 28 U.S.C. § 1332 (2006). DiBartolo is a resident of New York; Abbott is a corporation registered in Illinois; and the amount in controversy, exclusive of interest and costs, is "in the millions of dollars" — clearly above the $75,000 statutory

threshold. Am. Compl. ¶ 81; see also 28 U.S.C. § 1332. Abbott did not challenge personal jurisdiction in its motion to dismiss and thus waived any objection to personal jurisdiction. See Fed. R. Civ. P. 12(b)(2), (h)(1); Bates v. C & S Adjusters, Inc., 980 F.2d 865, 868 n.1 (2d Cir. 1992). Finally, venue is proper because "a substantial part of the events or omissions giving rise to the claim" occurred in this District. 28 U.S.C. § 1391(b). DiBartolo was prescribed Humira here, underwent treatment here, and suffered the alleged harm here. Am. Compl. ¶¶ 54-69.

B. Legal Standard

When a court evaluates a motion to dismiss for failure to state a claim, pursuant to Federal Rule of Civil Procedure 12(b)(6), it must accept as true all well-pleaded facts alleged in the complaint and must draw all reasonable inferences in the plaintiff's favor. Kassner v. 2nd Ave. Delicatessen, Inc., 496 F.3d 229, 237 (2d Cir. 2007). Mere "conclusions of law or unwarranted deductions of fact" need not be accepted as true. First Nationwide Bank v. Gelt Funding Corp., 27 F.3d 763, 771 (2d Cir. 1994). A complaint must include "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Where plaintiffs have not "nudged their claims across the line from conceivable to plausible, their complaint must be dismissed." Id. This

pleading standard applies in "all civil actions." Ashcroft v. Iqbal, 556 U.S. 662, 684 (2009). A court deciding a motion under Rule 12(b)(6) may "properly consider 'matters of which judicial notice may be taken, or documents either in plaintiff['s] possession or of which plaintiff[] had knowledge and relied on in bringing suit.'" Halebian v. Berv, 644 F.3d 122, 130 n.7 (2d Cir. 2011) (quoting Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002)). In particular, "[i]t is well established that a district court may rely on matters of public record in deciding a motion to dismiss under Rule 12(b)(6)." Pani v. Empire Blue Cross Blue Shield, 152 F.3d 67, 75 (2d Cir. 1998).

C. Choice of Law

Both parties agree that New York law should apply to this case. Am. Compl. ¶¶ 78-82; Mem. of Law in Supp. of Def.'s Mot. to Dismiss Pl.'s Compl. 7-8 [hereinafter Def.'s Mot. to Dismiss]. "Where jurisdiction rests upon diversity of citizenship, a federal court sitting in New York must apply the New York choice-of-law rules . . ." Stuart v. Am. Cyanamid Co., 158 F.3d 622, 626 (2d Cir. 1998). Under New York law, "'controlling effect' must be given 'to the law of the jurisdiction which, because of its relationship or contact with the occurrence or the parties, has the greatest concern with the specific issue raised in the litigation.'" Schultz v. Boy

Scouts of Am., Inc., 65 N.Y.2d 189, 196 (1985) (quoting Babcock v. Jackson, 12 N.Y.2d 473, 481 (1963)).

Here, DiBartolo is a resident of New York, was prescribed Humira in New York, purchased and used Humira in New York, and suffered injury in New York. It therefore appears that New York has the strongest interest in this case. Although DiBartolo suggests that the law of Illinois — the state of Abbott's domicile — might apply here, she frames her claims primarily in terms of New York law and does not argue that Illinois law should apply. The Court will therefore apply the substantive law of New York.

D. Analysis

Plaintiff's amended complaint, read broadly, alleges eight causes of action: (1) strict products liability based on failure to warn, (2) negligent failure to warn, (3) strict products liability based on design defect, (4) negligent design defect, (5) strict liability misrepresentation, (6) negligent misrepresentation, (7) breach of express warranty, and (8) breach of the implied warranty of merchantability. Am. Compl. ¶¶ 78-80.

A claim for strict products liability arises where "(1) the product is defective, and (2) the defect caused plaintiff's injury." Lewis v. Abbott Labs., No. 08 Civ. 7480, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009) (citing Colon ex rel.

Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 82 (S.D.N.Y. 2001)). A negligence claim arises where "(1) 'the manufacturer owed plaintiff a duty to exercise reasonable care;' (2) the manufacturer breached that duty by failing to use reasonable care so that the product was rendered defective; (3) 'the defect was the proximate cause of the plaintiff's injury; and' (4) plaintiff suffered 'loss or damage.'" Id. (quoting Colon, 199 F. Supp. 2d at 82).

1. Failure to Warn

Plaintiff's first two causes of action are for strict liability and negligence based on failure to warn. Under New York law, "[f]ailure to warn claims are identical under strict liability and negligence theories of recovery." Lewis, 2009 WL 2231701, at *5 (quoting Colon, 199 F. Supp. 2d at 84) (internal quotation marks omitted). Here, plaintiff adequately alleges that her injury was caused by Abbott's failure to warn, Am. Compl. ¶¶ 43, 56, and that she suffered damages as a result, id. ¶¶ 59-69. The remaining issues are the scope of Abbott's duty to warn and whether Abbott breached that duty. These issues will be addressed in turn.

a. The Scope of Abbott's Duty to Warn Is Governed by New York's Informed Intermediary Doctrine

Under New York law, a pharmaceutical manufacturer has a duty "to warn of all potential dangers in its prescription drugs

that it knew, or, in the exercise of reasonable care, should have known to exist." Martin v. Hacker, 83 N.Y.2d 1, 8 (1993). The New York Court of Appeals has adopted the Informed Intermediary Doctrine ("IID"), also known as the "Learned Intermediary Doctrine," which provides that a drug manufacturer's duty is to warn the treating physician, not the patient:

> Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an "informed intermediary" between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient. The warning must provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with the drug.

Id. at 9 (citations omitted).[3] To state a prima facie claim for failure to warn, "[a] plaintiff must demonstrate [1] that the

[3] Contrary to plaintiff's argument, IID is not an affirmative defense under New York law, but rather defines the scope of a drug manufacturer's duty to warn of the risks of its drugs. See Martin, 83 N.Y.2d at 9. It is immaterial that, in two other currently pending cases, Abbott has pled under the category of "Affirmative Defenses" that "Plaintiff's claims are barred in whole or in part by the learned intermediary doctrine." Def. Abbott Labs.' Answer to Pl.'s Compl. 20, Bixby v. Abbott Labs., No. 1:11-cv-03414 (N.D. Ill. July 25, 2011) [hereinafter Bixby Answer]; Def. Abbott Labs.' Answer and Affirmative Defenses to Pls.' Compl. 52, Gioeli v. Abbott Labs., No. 11 L 004270 (Ill. Cir. Ct. Cook Cnty. Mar. 2, 2012) [hereinafter Gioeli Answer]. Even putting aside that the form of Abbott's pleadings in other cases does not alter New York law, the pleadings on their face do not support DiBartolo's position that IID is an affirmative defense. The "Affirmative Defenses" section of each pleading begins by stating: "Abbott asserts the following defenses on information and belief in response to the allegations contained in Plaintiff's complaint, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such

warning was inadequate and [2] that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries." Glucksman v. Halsey Drug Co., 160 A.D.2d 305, 307 (N.Y. App. Div. 1st Dep't 1990); see also Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009).

In determining whether a warning is adequate as a matter of law or presents a question of fact for the jury, New York courts "evaluate the [warning]'s language for its accuracy, clarity and relative consistency." Martin, 83 N.Y.2d at 11.[4] A warning is accurate if it is "correct, fully descriptive and complete, and . . . convey[s] updated information as to all of the drug's known side effects." Id. (citation omitted). A warning is clear if it employs language that is "direct, unequivocal and sufficiently forceful to convey the risk." Id. An otherwise clear warning "may be obscured by inconsistencies or contradictory statements made in different sections of the package insert regarding the same side effect or from language

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defenses are denominated herein." Bixby Answer 19; Gioeli Answer 52. Abbott's listing of IID under "Affirmative Defenses" was not an admission that the doctrine is an affirmative defense, but rather appears to have been simply the product of a conservative litigation strategy. See Reply Mem. of Law in Supp. of Def.'s Mot. to Dismiss Pl.'s Compl. 4 [hereinafter Def.'s Reply].

[4] As the motion presently before the Court is a motion to dismiss for failure to state a claim, the dispositive inquiry is whether the amended complaint alleges sufficient facts to state a plausible claim for relief, see Twombly, 550 U.S. at 570, not whether judgment for either party as a matter of law is warranted. That said, the factors that inform whether a warning is adequate under New York law are relevant to evaluating whether plaintiff's amended complaint states a claim for failure to warn.

in a later section that dilutes the intensity of a caveat made in an earlier section." Id. However, even a warning with such contradictions may be adequate "if the language of a particular admonition against a side effect is precise, direct, and unequivocal and has sufficient force." Id. at 12. Finally, a court evaluates the warning as a whole, as any vagueness that appears from reading individual sentences in isolation "may be overcome if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." Id.

An important principle that follows from this analysis is that a warning does not adequately warn of a side effect simply by stating that the side effect may result from use of the drug. Rather, a warning's adequacy depends on the specific manner in which the warning advises physicians of the risk that the side effect will materialize. Courts applying New York law have accordingly denied summary judgment to pharmaceutical manufacturers where the warnings mentioned the side effect suffered by the plaintiff but failed to warn of the side effect in a manner that was sufficiently accurate, clear, and consistent. See, e.g., In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., 817 F. Supp. 2d 535, 555 (E.D. Pa. 2011) (denying defendant's motion for summary judgment on a failure-to-warn claim, based on the law of New York as well as three other states, because "a reasonable jury could conclude that

although the 2001 and 2007 labels warned about [Congestive Heart Failure] risks, they did not do so specifically enough or directly enough"). In the context of a motion under Rule 12(b)(6), the important point is that a failure-to-warn claim will not be dismissed if the complaint sufficiently alleges that the manufacturer, although it warned of the side effect suffered by the plaintiff, failed to warn of the side effect adequately.

Furthermore, courts applying New York law have held that "prescription medicine warnings are adequate when . . . information regarding 'the precise malady incurred' was communicated in the prescribing information." In re Accutane Prods. Liab., MDL No. 1626, 2012 WL 3194954, at *5 (M.D. Fla. July 24, 2012) (quoting Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284-85 (S.D.N.Y. 2009)); see also Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 260 (E.D.N.Y. 1999) (granting summary judgment to drug manufacturer where manufacturer had warned physician "against the precise usage and injuries in question"). The language of these decisions might at first seem to indicate that a manufacturer satisfies its duty to warn of a drug's side effects simply by mentioning those side effects in the drug's label. In fact, each of these decisions, consistent with the weight of New York authority, considered not merely the existence of a pertinent warning, but also the qualitative adequacy of the warning. See In re Accutane Prods. Liab., 2012

WL 3194954, at *5 (finding that "[t]he Physician Package Insert plainly and prominently identified [the relevant side effect] by name . . . in the "WARNINGS" and "ADVERSE REACTIONS" sections of the insert"); Alston, 670 F. Supp. 2d at 284-85 (noting that the drug label "is unequivocal in warning about the injuries allegedly sustained by Plaintiff and by providing Plaintiff's physician with specific detailed information on the risks of the [product]" (alteration in original) (internal quotation mark omitted)); Sita, 43 F. Supp. 2d at 260 ("[D]espite plaintiff's claims to the contrary, there can be no dispute that the package insert contained language that adequately warned against the precise usage and injuries in question." (emphasis added)). It follows that a court deciding a failure-to-warn claim under New York law must consider not merely the existence of a relevant warning, but also the qualitative adequacy of that warning.

b. Plaintiff Has Not Shown that an Exception to IID Applies Here

Plaintiff argues in her amended complaint that the Court should decline to apply IID because Abbott marketed Humira through Direct-to-Consumer ("DTC") advertising, Am. Compl. ¶¶ 20-28, and because Dr. Cui may have had a direct financial relationship with Abbott, id. ¶¶ 12-19. However, DiBartolo has failed to establish that either of these alleged facts, even if taken as true, constitutes an exception to IID.

First, DiBartolo argues that Abbott engaged in "extensive marketing in the public domain," id. ¶ 20, and that this DTC marketing constitutes an exception to IID. Br. in Supp. of Resp. to Mot. to Dismiss 21-24 (June 15, 2012) [hereinafter Pl.'s Opp'n]. DiBartolo urges the Court to predict that the New York Court of Appeals will adopt Section 6(d) of the Restatement (Third) of Torts: Products Liability, which provides:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts: Prods. Liab. § 6(d) (1998); see also Am. Compl. ¶¶ 50-52; Pl.'s Opp'n 23. Plaintiff contends that the Restatement supports finding an exception to IID here because "Abbott has engaged in the use of mass media to promote the drug directly to consumers like Cynthia DiBartolo, and . . . such DTC advertisements directly influenced Plaintiff's decision to take this drug." Pl.'s Opp'n 23.[5]

[5] Plaintiff also cites comment e to section 6, Am. Compl. ¶ 50, which notes that "arguments have been advanced" in favor of an exception to IID where "manufacturers have advertised a prescription drug and its indicated use in the mass media." Restatement (Third) of Torts: Prods. Liab. § 6, cmt. e. But comment e does not endorse such an exception. Rather, it "leaves to developing case law whether exceptions to the learned intermediary rule in

Contrary to plaintiff's assertions, section 6 would not support finding an exception to IID here even if it were good law in New York and even assuming that Abbott extensively marketed Humira to the public. This is not a case "when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings." Restatement (Third) of Torts: Prods. Liab. § 6(d). Dr. Cui met with DiBartolo individually prior to prescribing her Humira, and he was well placed during this visit both to evaluate whether Humira's benefits to DiBartolo justified its risks and to provide DiBartolo with whatever instructions or warnings were necessary. Plaintiff's amended complaint fails to provide any reason why Abbott could not have reasonably expected such an

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these or other situations should be recognized." Id. New York case law, as discussed below, has not recognized a DTC exception.

Comment e also suggests, without taking a position, that an exception to IID applies where "governmental regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug." Id. Plaintiff argues that this exception may apply here because the FDA mandated that Abbott provide a Medication Guide directly to patients. Am. Compl. ¶ 50. As with the purported DTC exception, however, New York courts have not endorsed an exception to IID where the FDA has required drug manufacturers to distribute Medication Guides. Although several decisions applying New York law have included language suggesting such an exception, see, e.g., Krasnopolsky v. Warner-Lambert Co., 799 F. Supp. 1342, 1346 (E.D.N.Y. 1992), courts have consistently applied IID to failure-to-warn claims involving drugs for which patients were provided Medication Guides, see, e.g., In re Accutane Prods. Liab., MDL No. 1626, 2012 WL 3194954 (M.D. Fla. July 24, 2012) (applying New York law); Snyder v. Hoffman-LaRoche, Inc., No. 8:07-cv-1282-T-30TBM, 2008 WL 4790666 (M.D. Fla. 2008) (same). Additionally, it is notable that the FDA required Abbott to distribute a Medication Guide because of the risk of infection, not the risk of NMSC, and plaintiff has not alleged that the FDA required Abbott to warn patients specifically of the risk of NMSC. See Letter from FDA to Abbott (Jan. 18, 2008), at 4.

individualized medical assessment to be conducted every time a physician prescribed a patient Humira.

Not only did Abbott expect that prescribing physicians would evaluate whether Humira was a medically appropriate treatment for their patients, but it also expected that physicians would closely monitor their patients during the patients' course of treatment. As plaintiff acknowledges, New York law presumes that "a user would have heeded warnings if they had been given." Am. Compl. ¶ 53 n.16 (quoting Adesina v. Aladan Corp., 438 F. Supp. 2d 329, 338 (S.D.N.Y. 2006)). Here, the Humira label in use in November 2008 warned physicians that "HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician." Humira Label, at 4. Although Dr. Cui did not in fact monitor DiBartolo, Abbott could have relied on the New York presumption and thus reasonably expected Dr. Cui to heed the warning clearly stated in the Humira label. In other words, the fact that DiBartolo was not monitored during the time she took Humira might speak to the level of care she received from Dr. Cui, but is not attributable to Abbott.

At any rate, section 6 of the Restatement (Third) of Torts: Products Liability is not good law in New York. Although lower New York courts have cited the section, see Militrano ex rel. Militrano v. Lederle Labs., 769 N.Y.S.2d 839, 851 (Sup. Ct.

2003); Tenuto v. Lederle Labs., 181 Misc. 2d 367, 370-71 (N.Y. Sup. Ct. 1999), the New York Court of Appeals has not adopted it, as plaintiff concedes, see Am. Compl. ¶ 51, and plaintiff cannot even cite an Appellate Division decision adopting the section. It is immaterial that the Court of Appeals has adopted other sections of the Restatement (Third) of Torts: Products Liability. Contrary to plaintiff's suggestion, moreover, there is no trend in favor of recognizing a DTC exception. See Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006) (noting that Perez v. Wyeth Labs., Inc., 734 A.2d 1245 (N.J. 1999) established a DTC exception under New Jersey law, but that "in the eight years since Perez, . . . no state has joined New Jersey").

Finally, plaintiff relies on Murthy v. Abbott Labs., 847 F. Supp. 2d 958 (S.D. Tex. 2012), and Samuels v. Am. Cyanamid Co., 495 N.Y.S.2d 1006 (Sup. Ct. 1985), Pl.'s Opp'n 22-23, but neither decision is controlling or on point. In Murthy, the Southern District of Texas predicted that the Texas Supreme Court would apply a DTC exception based in large part on an intermediate Texas appellate court decision that did so. Murthy, 847 F. Supp. 2d at 970-71 (citing Centocor, Inc. v. Hamilton, 310 S.W.3d 476 (Tex. Ct. App. 2010)). This prediction turned out to be incorrect; in June of this year, the Texas Supreme Court reversed the appellate court decision relied on in

Murthy and held that, regardless of whether a DTC exception might apply in certain cases, no such exception applied in the case at bar. Centocor, Inc. v. Hamilton, 372 S.W.3d 140 (Tex. 2012). In Samuels, the New York Supreme Court declined to apply IID where the plaintiff received a vaccine from nurses at a company clinic operating under a "general authorization" from a doctor. Samuels, 495 N.Y.S.2d at 1010. The circumstances were such that the vaccine manufacturer "should [have] know[n] or ha[d] reason to know that the vaccines [we]re customarily administered without any meaningful appraisal by an 'informed intermediary.'" Id. at 1013. Here, by contrast, DiBartolo was prescribed Humira only after an individual meeting with Dr. Cui, and Abbott had no reason to think that Humira would be prescribed in any other way.

In short, plaintiff fails to establish that New York courts would apply a DTC exception to IID. In reaching this conclusion, we do not deny that DTC advertising has "altered the traditional doctor patient relationship." Pl.'s Opp'n 2; see also Am. Compl. 3 n.1. Even in a world with widespread DTC advertising, however, physicians continue to fulfill the core functions that underlie IID: they "evaluate a patient's needs, assess the risks and benefits of available drugs and then prescribe a drug, advising the patient of its risks and possible side effects." Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61 (N.Y.

App. Div. 4th Dep't 1979), aff'd, 52 N.Y.2d 768 (1980). The physician therefore remains an "informed intermediary" to whom manufacturers should direct prescription drug warnings. Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980); Martin v. Hacker, 83 N.Y.2d 1, 9 (1993); Wolfgruber, 72 A.D.2d at 61. Indeed, although it may be true that DTC advertising encourages patients to ask specifically for the advertised drug, Am. Compl. ¶ 20, a physician who prescribed a drug to a patient simply based on the patient's request, without an individualized medical assessment, would likely be liable for malpractice. In such a situation, a failure-to-warn claim against the manufacturer would raise a serious issue of causation.

In addition to arguing for a DTC exception to IID, plaintiff contends that this Court should decline to apply IID because Abbott allegedly provided direct compensation to Dr. Cui. Plaintiff cites Murthy for the proposition that "when a physician is compensated by a drug company, some of the assumptions underlying the learned intermediary doctrine no longer hold." Pl.'s Opp'n 19 (quoting Murthy v. Abbott Labs., 847 F. Supp. 2d 958, 971 (S.D. Tex. 2012)). Plaintiff alleges that here, Abbott compensated physicians in various ways, Am. Compl. ¶¶ 12-19 & n.8, though she concedes that she "does not yet know to what extent Abbott either paid Dr. Cui, or exerted

other influences on him that would 'diminish' his 'role as the neutral decision-maker.'" Pl.'s Opp'n 20.

This argument fails on both the law and the facts. On the law, plaintiff has not cited any New York decision that adopts an exception to IID where physicians received compensation from drug manufacturers. Murthy applied Texas law, Murthy, 847 F. Supp. 2d 958, and plaintiff has not demonstrated that Murthy is part of any trend supporting an exception to IID where drug manufacturers compensate physicians.[6] On the facts, moreover, plaintiff's allegations that Abbott compensated Dr. Cui are completely speculative, based entirely on what Abbott allegedly did in other cases involving other physicians. In sum, plaintiff has failed to show that Abbott's alleged DTC advertising or its (speculatively) alleged compensation of Dr. Cui provide reason for this Court not to apply IID - a doctrine firmly established in New York law.

c. Plaintiff Has Adequately Alleged Failure to Warn

As set out above, Abbott provided, per FDA regulations, a detailed label to physicians prescribing Humira and a shorter Medication Guide to patients being treated with Humira. The

[6] Looking more broadly to IID's rationale, plaintiff has not demonstrated that an exception to IID would be justified even if one assumes that physicians compensated by Abbott would be more likely to prescribe Humira than to prescribe a competitor drug. Such physicians would not be absolved of their duty to prescribe drugs to patients only when medically appropriate. It is not clear, moreover, that manufacturer-compensated physicians would in fact neglect their professional duties to an extent that would undermine IID.

Humira label used throughout the course of DiBartolo's Humira treatment advised that "[m]alignancies [] are seen more often than in controls" and that "[d]uring the controlled portions of HUMIRA . . . plaque psoriasis trials, the rate (95% confidence interval) of non-melanoma (basal cell and squamous cell) skin cancers was 0.9 (0.57, 1.35)/100 patient-years among HUMIRA-treated patients and 0.3 (0.08, 0.80)/100 patient-years among control patients." Humira Label, at 1, 7. The label included the caveat that "[t]he potential role of TNF blocking therapy in the development of malignancies is not known." Id. at 7. Later in the label, Abbott warned that "[t]he possibility exists for TNF blocking agents, including HUMIRA, to affect host defenses against infections and malignancies since TNF mediates inflammation and modulates cellular immune responses." Id. at 9. Again, the label cautioned that "[t]he impact of treatment with HUMIRA on the development and course of malignancies, as well as active and/or chronic infections, is not fully understood." Id.

The label additionally warned that "[t]he most serious adverse reactions" of Humira included malignancies. Id. The label explained that "[m]ore cases of malignancy have been observed in HUMIRA-treated patients compared to control-treated patients in clinical trials." Id. at 10. Regarding "[o]ther [a]dverse [r]eactions," the label warned that "[o]ther

infrequent serious adverse reactions occurring at an incidence of less than 5% in rheumatoid arthritis patients treated with HUMIRA were: . . . Neoplasia: Adenoma, carcinomas such as breast, gastrointestinal, skin, urogenital, and others." Id. at 12-13. In light of these significant risks, the label admonished that "HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician." Id. at 3-4.

Abbott also distributed to Humira patients a Medication Guide, which warned that "[s]erious side effects, which sometimes lead to death, have happened in patients taking HUMIRA," including "[c]ertain types of [c]ancer." Humira Medication Guide, attached to Humira Label, at 36. In particular, the Medication Guide warned patients:

> There have been cases of certain kinds of cancer, in patients taking HUMIRA or other TNF blockers. Some patients receiving HUMIRA have developed types of cancer called nonmelanoma skin cancer (basal cell cancer and squamous cell cancer of the skin), which are generally not life-threatening if treated. Tell your doctor if you have a bump or open sore that doesn't heal.

Id. The Medication Guide was reprinted at the end of the Humira label, so the warnings it contained were also transmitted to physicians. See Humira Label, at 33-43.

Plaintiff argues that the warnings contained in the label and Medication Guide inadequately warned her and Dr. Cui of the

risk of developing NMSC. In support of her position, she references the label for Remicade, another TNF-blocking drug indicated for treatment of psoriasis. Id. ¶ 73. According to plaintiff, "Abbott scientists have admitted that Remicade and Humira have essentially the same presumed mode of action and general safety profile." Id. ¶ 74.

Unlike the Humira label used in November 2008, the Remicade label used in September 2006 – the month in which the FDA first approved Remicade for the treatment of psoriasis – warned that psoriasis patients with a history of PUVA treatment faced an increased risk of NMSC. Specifically, the Remicade label warned: "Psoriasis patients should be monitored for nonmelanoma skin cancers (NMSCs), particularly those patients who have had prior prolonged phototherapy treatment. In the maintenance portion of clinical trials for REMICADE, NMSCs were more common in patients with previous phototherapy . . . ." Id. ¶ 73 (quoting Remicade Label, Sept. 2006, at 31, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/103772s5129lbl.pdf [hereinafter Remicade Label]); see also Letter from Susan Walker, FDA, to Patricia Palumbo, Centocor, Inc. (Sept. 26, 2006), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/103772s5129ltr.pdf (approving request to include new Remicade indication for treatment of plaque psoriasis). Additionally, the September 2006 Remicade

Medication Guide, distributed to patients as well as included at the end of the label, contained the following warning:

> **What should I tell my doctor before starting treatment with REMICADE?**
>
> Your doctor will assess your health before each treatment.
>
> Tell your doctor about all of your medical conditions, including if you:
>
> . . .
>
> have had phototherapy (treatment with ultraviolet light or sunlight along with a medicine to make your skin sensitive to light) for psoriasis. You may have a higher chance of getting skin cancer while receiving REMICADE.

Am. Compl. ¶ 73 (quoting Remicade Medication Guide, attached to Remicade Label, at 50-51).

DiBartolo alleges that "[b]y not including similar language in [its] label, Abbott failed to appropriately warn patients and doctors, misrepresented the safety profile of Humira, and improperly led patients to believe that Humira was fit for their use." Id. ¶ 74. According to the amended complaint, had Abbott adequately warned of DiBartolo's increased risk for NMSC based on her history of PUVA treatment, DiBartolo would have "had a different discussion with her dermatologist" and would have "refused the medication," or at least "[e]nsured she was appropriately screened and monitored for NMSC." Id. ¶ 77. "Either action" – a decision not to take Humira or to take

Humira with adequate screening and monitoring for NMSC – "would have completely negated or otherwise minimized" DiBartolo's injuries. Id.

As discussed above, a pharmaceutical manufacturer does not necessarily discharge its duty to warn by simply noting that a drug is associated with an increased risk of a particular side effect. Rather, New York courts "evaluate the [warning]'s language for its accuracy, clarity and relative consistency," inquiring into whether the warning is "correct, fully descriptive and complete." Martin v. Hacker, 83 N.Y.2d 1, 11 (1993); see, e.g., In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., 817 F. Supp. 2d 535, 555 (E.D. Pa. 2011). A manufacturer, moreover, must warn physicians of all risks that "it knew, or, in the exercise of reasonable care, should have known to exist." Martin, 83 N.Y.2d at 8.

Here, although the Humira label clearly warned physicians that patients taking Humira face an increased risk of NMSC, plaintiff has adequately alleged that Abbott's warning was nonetheless inadequate. Taking as true plaintiff's allegations that Remicade poses an unusually high risk of NMSC to patients with a history of PUVA treatment, and that Remicade has the "same presumed mode of action and general safety profile" as Humira, Am. Compl. ¶ 74, it is "plausible," Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007), that Humira also poses an

unusually high risk of NMSC to patients with a history of PUVA treatment, Am. Compl. ¶¶ 42, 71. Because the Remicade label referenced by plaintiff was publically available as of September 2006, it is plausible that Abbott knew of this enhanced risk well before plaintiff was prescribed Humira in November 2008. Id. Moreover, if aware of this risk, Abbott would have had a duty to warn of it in the Humira label, but did not do so. Am. Compl. ¶¶ 42, 46. Had Dr. Cui received a proper warning, plaintiff alleges, he either would not have prescribed her Humira at all or would have prescribed it and provided sufficient warning, screening, and monitoring. Am. Compl. ¶¶ 43, 56. Plaintiff therefore adequately alleges that Abbott's omission was the proximate cause of her injury, a determination we make while acknowledging that plaintiff may encounter serious issues when the time comes to prove causation, in light of the extent to which Dr. Cui did or did not heed the warnings Abbott in fact provided. Finally, plaintiff sufficiently alleges that she suffered damages. Id. ¶¶ 59-69. DiBartolo therefore states a claim for failure to warn by alleging that Abbott did not warn physicians that patients with a history of PUVA treatment face an unusually high risk of NMSC.

In this regard, defendant contends that plaintiff does not state a claim because she "does not explain why the warning that all [Humira] patients face an increased risk of cancer was

insufficient to apprise her physician of the relevant risk." Def.'s Mot. to Dismiss 20 n.10. In support of its argument, defendant cites Barnes v. Kerr Corp., 418 F.3d 583 (6th Cir. 2005), which addressed a products liability suit by a dentist against the manufacturer of dental amalgams. The Barnes court held that the manufacturer satisfied its duty to warn by warning of the dangers posed by the mercury in its products, without also warning that those dangers remained when the mercury was combined with other ingredients. Id. at 591.

Barnes, however, applied Tennessee law and is distinguishable on the facts. The warning in Barnes, though it neglected to clarify that the risks of mercury were not neutralized by other ingredients, did state the actual level of risk that the product posed to consumers. The Humira label, by contrast, while stating the level of risk faced by Humira patients generally, did not specify the higher level of risk faced by patients with a history of PUVA treatment. Thus, plaintiff has adequately pled that the Humira label was not, unlike the warning in Barnes, "correct, fully descriptive and complete." Martin v. Hacker, 83 N.Y.2d 1, 11 (1993).

Although Abbott's omission of information regarding the risks to patients with a history of PUVA treatment supports a claim for failure to warn, the three sentences in the Humira label singled out for criticism in plaintiff's amended complaint

do not. Plaintiff alleges that the following assertions in the Humira label were "unclear and inconsistent":

> The size of the control group and limited duration of the controlled portions of studies precludes the ability to draw firm conclusions.
>
> These malignancies in HUMIRA-treated and control-treated patients were similar in type and number to what would be expected in the general population.
>
> The potential role of TNF blocking therapy in the development of malignancies is not known.

Am. Compl. ¶ 71 (quoting Humira Label, at 7). Focusing in particular on the final statement, plaintiff cites "information and belief based on review of internal documents marked confidential by Abbott" to argue that Abbott "knew – prior to Ms. DiBartolo being prescribed Humira – that Humira placed patients at increased risk of NMSC." Id. DiBartolo also alleges that Abbott "was aware that psoriasis patients who received PUVA treatment were at even higher risk for developing NMSC." Id. Finally, DiBartolo claims that "Abbott also knew, or should have known, that all patients taking Humira should be screened for NMSC both prior to and after being prescribed Humira," especially psoriasis patients "who had a history of PUVA treatments." Id. ¶ 72.

Plaintiff fails to demonstrate that the three referenced statements are misleading. Indeed, plaintiff appears simply to misunderstand them. Plaintiff focuses most on the statement

that "[t]he potential role of TNF blocking therapy in the development of malignancies is not known." Am. Compl. ¶ 71 (quoting Humira Label, at 7). The label includes a similar caveat later on, noting that "[t]he impact of treatment with HUMIRA on the development and course of malignancies . . . is not fully understood." Humira Label, at 9. Neither of these statements denies that Abbott knew of an association between Humira use and an increased risk of NMSC, nor do they conflict with warnings of that association elsewhere in the label. Instead, the statements indicate merely that Abbott had not identified a causal mechanism linking Humira use to malignancies. Especially given that the warnings in the Humira label were intended for physicians, not patients, see Martin v. Hacker, 83 N.Y.2d 1, 9 (1993), there was little to no risk that these statements would be misinterpreted to deny an association between Humira use and NMSC. See Def.'s Mot. to Dismiss 18-19.

Plaintiff also criticizes the statement that "[t]he size of the control group and limited duration of the controlled portions of studies precludes the ability to draw firm conclusions." Am. Compl. ¶ 71 (quoting Humira Label, at 7). But this statement does not apply to the risk of NMSC. Rather, it qualifies the findings of the studies described in the preceding sentence, involving "malignancies[] other than lymphoma and nonmelanoma (basal cell and squamous cell) skin

cancer." Humira Label, at 6-7. Finally, plaintiff objects to the statement that "[t]hese malignancies in HUMIRA-treated and control-treated patients were similar in type and number to what would be expected in the general population." Am. Compl. ¶ 71 (quoting Humira Label, at 7). Again, plaintiff misreads the sentence. As defendant observes, the sentence refers to malignancies "other than lymphoma and non-melanoma skin cancer." Def.'s Mot. to Dismiss 19 n.9. In short, the three sentences plaintiff criticizes do not undermine the warnings elsewhere in the label that Humira treatment is associated with an increased risk of NMSC. Plaintiff's additional arguments in support of her failure-to-warn claim are similarly unavailing. [7] As explained above, however, plaintiff states a failure-to-warn claim based on Abbott's omission of information on the enhanced risk of NMSC faced by patients with a history of PUVA treatment. Accordingly, defendant's motion is denied to the extent it relates to plaintiff's failure-to-warn claims.

2. Design Defect

Plaintiff asserts causes of action for strict liability and negligence based on design defect. Am. Compl. ¶¶ 78-79. As

[7] Plaintiff alleges that Abbott failed to warn adequately of the need to monitor for NMSC those patients with a history of PUVA treatment. Am. Compl. ¶¶ 42, 46. However, the Humira label explicitly warned that "HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician." Humira Label, at 4. This statement was plainly sufficient to warn that patients with a history of PUVA treatment, like all other Humira patients, should be closely monitored.

with failure to warn, "the analysis under strict liability and negligent design defect is identical." Steinman v. Spinal Concepts, Inc., No. 05-CV-774S, 2011 WL 4442836, at *8 (W.D.N.Y. Sept. 22, 2011); see also Lewis v. Abbott Labs., No. 08 Civ. 7480, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009).

To state a claim for defective design under New York law, a plaintiff must allege: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." Lewis, 2009 WL 2231701, at *4 (quoting Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001)); see also In re Nassau Cnty. Consol. MTBE (Methyl Tertiary Butyl Ether) Prods. Liab. Litig., 918 N.Y.S.2d 399 (Table), at *11 (Sup. Ct. 2010). The first two prongs function as a "risk-utility balancing test" to determine whether a product is unreasonably dangerous. Lewis, 2009 WL 2231701, at *4 (quoting Colon, 199 F. Supp. 2d at 84). According to the New York Court of Appeals, the relevant inquiry is "whether the product as designed was 'not reasonably safe' – that is, whether it is a product which, if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner." Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102,

108 (1983); see also Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 255 (E.D.N.Y. 1999). Finally, although defendant argues that New York law bars design defect liability if the manufacturer provided an adequate warning, Def.'s Mot. to Dismiss 9-12, this argument is irrelevant, even if true, in light of our conclusion that plaintiff states a claim for failure to warn.[8]

[8] Even if we had found that Abbott had provided an adequate warning, and we therefore had reason to consider its argument that an adequate warning bars design defect liability, there would be serious questions regarding defendant's interpretation of New York law. Defendant quotes Martin v. Hacker, 83 N.Y.2d 1 (1993), in which the New York Court of Appeals held that "even though its side effects may cause injury, a prescribed drug, accompanied by adequate warnings, is not defective, nor is it unreasonably dangerous." Def.'s Mot. to Dismiss 10 (quoting Martin, 83 N.Y.2d at 8) (internal quotation marks omitted). "Unreasonable dangerousness is, of course, the standard for design defect liability." Gensler v. Sanolfi-Aventis, No. CV-08-2255, 2009 WL 857991, at *6 (E.D.N.Y. Mar. 30, 2009) (citing Voss, 59 N.Y.2d at 106). Other decisions applying New York law have also included language that might indicate that a proper warning precludes a claim for defective design. See, e.g., Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 90-91 (2d Cir. 1980); In re Accutane Prods. Liab., MDL No. 1626, 2012 WL 3194954, at *6 (M.D. Fla. July 24, 2012); Wolfgruber v. Upjohn Co., 72 A.D.2d 59 (N.Y. App. Div. 4th Dep't 1979); Militrano ex rel. Militrano v. Lederle Labs., 769 N.Y.S.2d 839, 846-47 (Sup. Ct. 2003); Samuels v. Am. Cyanamid Co., 495 N.Y.S.2d 1006, 1011 (Sup. Ct. 1985).

Nonetheless, it is not clear that defendant's interpretation of New York law is correct. First, Martin, Lindsay, Wolfgruber, and Samuels each considered failure-to-warn claims but not design defect claims. Any indication that they gave regarding design defect claims is therefore dicta. See Gensler, 2009 WL 857991, at *6; Militrano, 769 N.Y.S.2d at 847. Second, although Militrano and Accutane considered design defect claims, they are not strong authority for defendant's argument that such claims are barred by an adequate warning. Militrano stopped short of deciding whether New York had in fact adopted such a rule, and Accutane's reasoning rested on the dicta in Martin. Third, when courts applying New York law have faced both failure to warn and design defect claims, and the plaintiff has failed to prove failure to warn, the courts have not found the design defect claims automatically barred, but rather have proceeded to analyze those claims. See, e.g., Lewis, 2009 WL 2231701; Lawrence v. Sofamor, S.N.C., No. 95-CV-1507, 1999 WL 592689 (N.D.N.Y. Aug. 2, 1999).

Plaintiff argues that Humira was defectively designed because all TNF-blockers, including Humira, have an "inherent defect": their "causal association" with cancer. Am. Compl. ¶ 7. Plaintiff later references "Humira's inherent defect - that it increases the risk of skin cancer in those who take it, particularly those patients like Cynthia who had previously undergone PUVA treatment." Id. ¶ 42.

These assertions fail to state a claim for defective design. First, plaintiff does not adequately allege that "[Humira] as designed posed a substantial likelihood of harm." Lewis v. Abbott Labs., No. 08 Civ. 7480, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009). Plaintiff concedes that the likelihood of harm from Humira-induced NMSC would have been minimal if Abbott had properly warned Dr. Cui and if Dr. Cui had adequately warned, screened, and monitored her:

> Had she been adequately warned of her increased risk for NMSC she would have had a different discussion with her dermatologist, when she was first prescribed Humira. If she had known of this risk, then she would have refused the medication. Even if she had decided to still take the drug, she would have insured she was appropriately screened and monitored for NMSC. Either action would have completely negated or otherwise minimized the traumatic ordeal she has suffered through and prevented the life altering and permanent damages she has sustained.

Am. Compl. ¶ 77. Thus, plaintiff admits that had she been "appropriately screened and monitored for NMSC," her injuries would have been "completely negated or otherwise minimized."

Id. Therefore, Humira did not pose "a substantial likelihood of harm" as designed. Lewis, 2009 WL 2231701, at *4.

Additionally, plaintiff does not adequately allege that "it was feasible to design [Humira] in a safer manner." Id. Plaintiff asserts that allegations of a safer alternative design are "implicit in the allegation of [the design defect] theory in ¶¶ 78-79 of the Amended Complaint." Pl.'s Opp'n 11. These paragraphs simply allege plaintiff's causes of action for strict liability and negligence, stating that "[a]dditional product liability theories include design defect," Am. Compl. ¶ 78, and that "Abbott was negligent in the design and testing of the drug Humira," id. ¶ 79. Essentially, plaintiff argues that it was unnecessary for her to include specific allegations that Abbott could have implemented an alternative design, and that it was sufficient simply to assert a claim for design defect.[9]

In fact, this argument has been squarely rejected by New York courts. The plaintiffs in Sabater ex rel. Santana v. Lead Industries Association, Inc., 704 N.Y.S.2d 800 (Sup. Ct. 2000), like DiBartolo, had argued that "failure to plead an alternative

[9] The only reference in the amended complaint to alternatives to Humira is the allegation that the "mode of action [of TNF-blockers such as Humira] speaks to the inherent defect found in Humira that is not seen in alternative forms of treatment for psoriasis." Am. Compl. ¶ 7. However, this broad reference to unnamed "alternative forms of treatment for psoriasis" is a far cry from a specific allegation that Humira could feasibly have been designed more safely. Indeed, we suspect that plaintiff's argument is directed less at the design of Humira and more at the manner in which Dr. Cui discharged his duty to evaluate which of several possible courses of treatment was most appropriate to treat plaintiff's psoriasis.

safer design is not a proper ground to attack a complaint as facially insufficient." Id. at 804. The court ruled that this argument was "unsupported by existing case law," noting that "[i]t is well settled that to establish a claim predicated upon a design defect, plaintiffs must present evidence that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and that it was feasible to design the product in a safer manner." Id. Because the plaintiffs had not adequately alleged a safer alternative design, the court dismissed their defective design claim. Id. at 804-05; see also Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 578 (E.D.N.Y. 2012) (granting drug manufacturer's motion to dismiss plaintiffs' design defect claim under New York and West Virginia law because "Plaintiffs do not plead facts alleging the existence of a feasible alternative design that would make the product safer"). DiBartolo's conclusory assertions in paragraphs 78 and 79 of her amended complaint, like the allegations in Sabater and Reed, fail to allege that defendant could have designed its drug more safely.[10] In short, plaintiff fails to allege that Humira posed a substantial likelihood of

[10] Contrary to plaintiff's assertions, Pl.'s Opp'n 11, plaintiff cannot wait until after discovery to allege facts showing an adequate alternative design. Nor may plaintiff cure her defective pleading "via Supplemental or Amended Complaint." Id.; see Fed. R. Civ. P. 15(a). Indeed, plaintiff suggests that she would use the opportunity to replead to allege scientific findings that a competitor drug was less likely than Humira to cause lymphoma, Pl.'s Opp'n 11-12, a suggestion that does not inspire confidence that plaintiff would use an opportunity to replead to cure the amended complaint's defects.

harm as designed or that Abbott feasibly could have designed Humira more safely. Accordingly, defendant's motion to dismiss is granted with respect to plaintiff's strict liability and negligent design defect claims.[11]

3. Misrepresentation

Plaintiff alleges causes of action for strict liability and negligent misrepresentation. Am. Compl. ¶¶ 78-79. Strict liability misrepresentation is described in section 402B of the Restatement (Second) of Torts:

> One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though
> (a) it is not made fraudulently or negligently, and
> (b) the consumer has not bought the chattel from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402B (1965). However, "New York has never adopted the strict liability approach set forth in Section 402B of the Restatement." Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 447-48 (W.D.N.Y. 2001) (quoting Loewy v. Stuart Drug & Surgical Supply, Inc., No. 91 Civ. 7148, 1999 WL 76939, at *6 (S.D.N.Y. Feb. 11, 1999)) (internal quotation mark

[11] Defendant argues that plaintiff also fails to plead the third element of a defective design claim, as she "fails to provide factual allegations establishing that the allegedly defective design was a substantial factor in causing her injury." Def.'s Mot. to Dismiss 13. Because plaintiff's causes of action based on defective design must be dismissed for failure to plead the first two elements, the Court does not reach whether plaintiff has adequately pleaded causation.

omitted). Accordingly, plaintiff's amended complaint is dismissed to the extent that it alleges a cause of action for strict liability misrepresentation.

Plaintiff also asserts a cause of action for negligent misrepresentation. Under New York law, a negligent misrepresentation claim normally requires "either actual privity of contract between the parties or a relationship so close as to approach that of privity." Marcellus Constr. Co., Inc. v. Village of Broadalbin, 302 A.D.2d 640, 640 (N.Y. App. Div. 3d Dep't 2003) (quoting Prudential Ins. Co. of Am. v. Dewey, Ballantine, Bushby, Palmer & Wood, 80 N.Y.2d 377, 382 (1992)). Absent privity of contract, plaintiff must demonstrate:

> (1) an awareness by the maker of the statement that it is to be used for a particular purpose; (2) reliance by a known party on the statement in furtherance of that purpose; and (3) some conduct by the maker of the statement linking it to the relying party and evincing its understanding of that reliance.

Marcellus Const. Co., 302 A.D.2d at 640-41 (quoting Rayco of Schenectady v. City of Schenectady, 267 A.D.2d 664, 665 (N.Y. App. Div. 3d Dep't 1999)). Plaintiff must also demonstrate that the statement contained "a false statement or material misrepresentation or omission." Prohaska, 138 F. Supp. 2d at 447 (citing Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 260 (E.D.N.Y. 1999)).

Here, although plaintiff's amended complaint includes numerous allegations that Abbott's Humira advertising was misleading, Am. Compl. ¶¶ 20-28, plaintiff cannot satisfy the elements of a claim for negligent misrepresentation. Plaintiff was not in privity of contract with Abbott, and she has not alleged that she was a "known party" to Abbott or that Abbott undertook specific conduct linking it to her and evincing its understanding of her alleged reliance on its ads. Thus, even assuming that plaintiff could meet the other elements of a negligent misrepresentation claim, her complaint would still be dismissed, to the extent that it alleges negligent misrepresentation, for failure to state a claim.

4. Breach of Warranty

Finally, plaintiff alleges that she relied on "the reputation and representations made by Abbott in its promotion of Humira," that "she had the right to expect Abbott to stand behind its product and to bear the burden for any injuries she sustained as a result of her use of its product," and that "Abbott has breached its warranty obligations under New York law." Am. Compl. ¶ 80. Plaintiff does not specify whether she asserts a claim for breach of express warranty or breach of the

implied warranty of merchantability, so both causes of action will be addressed here.[12]

a. Express Warranty

Under the U.C.C., "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." N.Y. U.C.C. § 2-313(1)(a) (McKinney 2012). Privity is normally "an essential element of a cause of action for express warranty," Carcone v. Gordon Heating & Air Conditioning Co., 212 A.D.2d 1017, 1018 (N.Y. App. Div. 4th Dep't 1995), but the U.C.C. includes a personal injury exception: "A seller's warranty whether express or implied extends to any natural person if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty." N.Y. U.C.C. § 2-318. Here, plaintiff does not show that she was in privity with defendant, but defendant could reasonably expect that plaintiff would "use,

[12] There is also a cause of action under the U.C.C. for breach of the implied warranty of fitness for a particular purpose: "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose." N.Y. U.C.C. § 2-315 (McKinney 2012). However, this cause of action is inapplicable here because DiBartolo was unknown to Abbott. Def.'s Reply 9 n.5.

consume or be affected by" Humira, and plaintiff alleges that she suffered personal injury. Am. Compl. §§ 55-69.

To state a claim for breach of express warranty, plaintiff must allege that "there was an affirmation of fact or promise by the seller, the natural tendency of which was to induce the buyer to purchase and that the warranty was relied upon to the plaintiff's detriment." Weiner v. Snapple Beverage Corp., No. 07 Civ. 8742, 2011 WL 196930, at *5 (S.D.N.Y. Jan. 21, 2011) (quoting Fendi Adele S.R.L. v. Burlington Coat Factory Warehouse Corp., 689 F. Supp. 2d 585, 604 (S.D.N.Y.2010)); Jones by Jones v. Lederle Labs., 695 F. Supp. 700, 709 (E.D.N.Y. 1988). The affirmation of fact or promise must have been "false or misleading when made." Shop Vac Corp. v. BCL Magnetics Ltd., No. 04-CV-262, 2005 WL 2739161, at *6 (N.D.N.Y. Oct. 24, 2005) (citing Rogath v. Siebenmann, 129 F.3d 261, 264 (2d Cir. 1997)). "Under New York law, an express warranty is part and parcel of the contract containing it and . . . [a] party injured by breach of contract is entitled to be placed in the position it would have occupied had the contract been fulfilled according to its terms." Weiner, 2011 WL 196930, at *5 (quoting Merrill Lynch & Co. v. Allegheny Energy, Inc., 500 F.3d 171, 184-85 (2d Cir. 2007)).

Here, plaintiff fails to state a claim for breach of express warranty. With regard to the Humira label, plaintiff

alleges that three statements were "unclear and inconsistent." Compl. ¶ 71. However, as determined supra at 33 to 36, two of these statements relate to risks other than the risk of NMSC, thus plaintiff could not have suffered detriment from relying on them. The third statement, regarding Abbott's lack of knowledge of a causal mechanism linking Humira to malignancies, has not adequately been alleged to be "false or misleading when made." Shop Vac Corp., 2005 WL 2739161, at *6; see Def.'s Mot. to Dismiss 18-19. With regard to the Humira Medication Guide, plaintiff does not even allege that a particular affirmation of fact or promise was false or misleading when made.

With regard to the Humira advertisements, plaintiff alleges that Abbott overrepresented the class of patients for whom Humira was appropriate. One Humira advertisement, printed in the American Academy of Dermatology Post Meeting News (the "AAD Ad"), represented that Humira was "approved for moderate to severe chronic plaque psoriasis," Am. Compl. ¶ 27, though Humira was in fact indicated for only those "moderate to severe chronic plaque psoriasis" patients "who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate," Humira Label, at 1. See Letter from Andrew S.T. Haffer, FDA, to Marry Ann Huizenga, Abbott Labs. (Dec. 16, 2008), att'd as Exh. D to Am. Compl, available at http://www.fda.gov/downloads/Drugs/GuidanceCompliance

RegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm053941.pdf [hereinafter Letter from FDA to Abbott (Dec. 16, 2008)]. The FDA accordingly informed Abbott that the ad was "misleading because it suggests that HUMIRA is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience." Id. at 3. The FDA elaborated that the truncated indication for Humira presented in the ad did not sufficiently convey that "the use of HUMIRA in plaque psoriasis [patients] needs to be very carefully considered." Id. Although the complete FDA-approved indication was included in another part of the ad, the method by which it was presented created an "overwhelming impression . . . [that] broadens the indication for HUMIRA." Id. at 4.

Even so, Abbott's overstatements do not constitute breach of express warranty because DiBartolo could not have relied on them to her detriment. DiBartolo fit within the class of patients for whom the FDA had approved Humira: she had previously received PUVA therapy to treat her psoriasis, and she switched to taking Humira presumably due to Dr. Cui's belief that Humira was medically more appropriate than continuing PUVA therapy. There is no indication to the contrary in plaintiff's amended complaint. It follows that plaintiff does not state a

claim for breach of express warranty based on Abbott's overrepresentation of the Humira indication.

Plaintiff also alleges that Abbott's advertisements misleadingly understated Humira's risks. With regard to Abbott's television advertisement, plaintiff concedes that Abbott warned that "[s]erious, sometimes fatal, events can occur, such as . . . cancer," but argues that these risks were "discount[ed]" because they were "read fairly quickly and significantly occluded by music," were not reinforced by the simultaneously presented visual images, and were not, unlike the benefits of Humira, quantified with specific study findings. Am. Compl. ¶¶ 21-22. Plaintiff alleges that the advertisement "sen[t] consistent audio and visual messages about the benefits, but inconsistent messages about the risks of Humira," id. ¶ 21, and that it failed to communicate that Humira increased patients' risk of NMSC, especially patients with a history of PUVA treatment, and that patients should be screened and monitored for NMSC, id. ¶ 24. With regard to the AAD Ad, plaintiff notes that the FDA determined:

> Th[e] overall presentation misleadingly minimizes the serious risks associated with HUMIRA because it fails to convey this important risk information with a prominence and readability reasonably comparable to the claims of effectiveness in the ad. The overall effect of this presentation undermines the communication of important risk information, minimizing the risks associated with HUMIRA and

> misleadingly suggesting that HUMIRA is safer than has been demonstrated.

Letter from FDA to Abbott (Dec. 16, 2008), at 4; see also Am. Compl. ¶ 27.

These allegations do not state a claim for breach of express warranty. With regard to the television advertisement, plaintiff alleges that the warnings Abbott provided were conveyed in an insufficiently forceful manner, but she does not allege a particular "affirmation of fact or promise" that was false or misleading. Although the advertisement as a whole might have emphasized Humira's benefits and downplayed its risks, a claim for breach of express warranty must rest on specific misleading statements, not entire advertisements or other collections of information that are allegedly misleading when viewed in the aggregate. Plaintiff's assertion that the television advertisement omitted certain warnings also does not allege a particular misleading statement and thus does not state a claim for breach of express warranty.

Nor do plaintiff's allegations regarding the FDA's findings. The FDA considered the AAD Ad as a whole and found it misleading, such that Humira was misbranded in violation of the Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301-399d (2006), and FDA implementing regulations. Letter from FDA to Abbott (Dec. 16, 2008) (citing 21 U.S.C. §§ 321(n), 352(n); 21

C.F.R. 202.1(e)(3)(i), (e)(5), (e)(6)(i), (e)(7)(viii) (2012)). This Court, however, is applying not the federal standard for a misbranded product, but rather the New York standard for breach of express warranty. As discussed above, the New York standard requires a specific "affirmation of fact or promise" that is false or misleading; it is not sufficient that an ad's "overall presentation" is misleading or that its "overall effect" is to communicate an inaccurate safety profile. In short, plaintiff has not alleged that Abbott included a false or misleading "affirmation of fact or promise" in the television ad, the AAD Ad, or any other DTC advertisement, other than the overstatement of Humira's indication, for which she cannot demonstrate detriment. Accordingly, defendant's motion is granted to the extent plaintiff asserts a claim for breach of express warranty.

b. Implied Warranty

An implied warranty of merchantability arises under the U.C.C. from any contract for the sale of goods where "the seller is a merchant with respect to goods of that kind." N.Y. U.C.C. § 2-314(1) (2012). As with a claim for breach of express warranty, privity is normally required for a claim for breach of implied warranty, though the U.C.C.'s personal injury exception applies here as well. See N.Y. U.C.C. § 2-318; Schwatka v Super Millwork, Inc., 939 N.Y.S.2d 744 (Table), at *2 (Sup. Ct. 2011) ("A cause of action based upon breach of an implied warranty

does not exist where there is no seller-buyer relationship or sales contract between the parties, and the plaintiff is not [an] injured person" (quoting Hole v. Gen. Motors Corp., 83 A.D.2d 715, 716 (N.Y. App. Div. 3d Dep't 1981)).

To state a claim for breach of the implied warranty of merchantability, a plaintiff must show, as she would for strict products liability or negligence claims, that "a defect in the product was a substantial factor in causing the injury and . . . that the defect complained of existed at the time the product left the manufacturer or entity in the line of distribution being sued." Macaluso v. Herman Miller, Inc., No. 01 Civ. 11496, 2005 WL 563169, at *4 (S.D.N.Y. Mar. 10, 2005) (quoting Tardella v. RJR Nabisco, Inc., 576 N.Y.S.2d 965, 966 (3d Dep't 1991)). The defect may arise from "a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product" - again similarly to strict products liability or negligence claims. Adesina v. Aladan Corp., 438 F. Supp. 2d 329, 345 (S.D.N.Y. 2006) (quoting Langer v. Well Done, Ltd., 815 N.Y.S.2d 494 (Table), at *2 (Sup. Ct. 2006)). With regard to how the plaintiff must demonstrate a defect, however, the tort-based causes of action for strict products liability and negligence part ways with the contract-

based cause of action for breach of implied warranty.[13] Under strict liability and negligence theories, a defect is proved by showing the elements of the standards set out above. Under a breach of implied warranty theory, by contrast, a plaintiff must show only that the goods in question are not "fit for the ordinary purposes for which such goods are used." N.Y. U.C.C. § 2-314(2) (2012); see also Macaluso, 2005 WL 563169, at *5. This analysis "focuses on the expectations of the product's performance when used in the customary, usual, and reasonably foreseeable manner." Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 449 (W.D.N.Y. 2001) (quoting Groome v. Matsushita Elec. Corp. of Am., No. 92 CV 3073, 2000 WL 341134, at *6 (E.D.N.Y. Mar. 30, 2000)).

Here, plaintiff states a claim for breach of the implied warranty of merchantability. Plaintiff alleges that Abbott failed to provide an adequate warning by omitting from the Humira label information regarding the increased risk of NMSC

[13] Defendant misreads New York law when it argues that breach of implied warranty and strict products liability are essentially the same cause of action. Def.'s Mot. to Dismiss 11. In Denny v. Ford Motor Co., 87 N.Y.2d 248 (1995), the Court of Appeals held that although "there is a high degree of overlap between the substantive aspects of the two causes of action" for strict products liability and breach of implied warranty, "it would not be correct to infer that the tort cause of action has completely subsumed the older breach of implied warranty cause of action or that the two doctrines are now identical in every respect." Id. at 256. That said, the precise boundaries of the causes of action for strict products liability (and negligence) and breach of implied warranty "remain[] 'unsettled.'" Davids v. Novartis Pharms. Corp., 857 F. Supp. 2d 267, 289 (E.D.N.Y. 2012) (quoting Davila v. Goya Foods, Inc., No. 05-CV-8067, 2007 WL 415147, at *1 n.1 (S.D.N.Y. Feb. 7, 2007)).

faced by patients with a history of PUVA treatment. This omission allegedly led DiBartolo to have inaccurate expectations about the risk she faced from the normal use of Humira. Plaintiff thus alleges that Humira was not fit for its ordinary purpose and so was defective for purposes of breach of implied warranty. This defect, moreover, existed at the moment the Humira label left Abbott's control. Finally, plaintiff adequately alleges that the defective warning was a substantial factor in causing her injury. Am. Compl. ¶¶ 43, 56. As with plaintiff's tort claims, serious issues may well arise here in the course of proving causation, given that Dr. Cui did not heed Abbott's warning to monitor DiBartolo.[14] At this early stage in the litigation, however, it is sufficient that adequate warnings might plausibly have averted some damage by leading DiBartolo not to take Humira or to take it with proper screening and monitoring. Plaintiff therefore states a claim for breach of implied warranty.[15]

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[14] Another issue that may arise is whether plaintiff's tumor pre-existed her Humira treatment, given that plaintiff received Humira injections for only six months.

[15] Given our previous finding that plaintiff states a strict liability/negligence claim based on failure to warn, see supra pp. 14-36, it is no surprise that she also states a claim for breach of implied warranty. "[A]s a practical matter, the distinction between the defect concepts in tort law and in implied warranty theory may have little or no effect in most cases[.]" Fritz v. White Consol. Indus., Inc., 762 N.Y.S.2d 711, 714 (4th Dep't 2003) (quoting Denny, 87 N.Y.2d at 262) (internal quotation marks omitted).

IV. Conclusion

For the foregoing reasons, defendant's motion to dismiss is granted in part and denied in part. Defendant's motion is granted to the extent that plaintiff alleges strict liability design defect, negligent design defect, strict liability misrepresentation, negligent misrepresentation, and breach of express warranty. Because plaintiff has already filed one amended complaint and has not demonstrated good cause why the Court should grant her leave to file a second amended complaint, plaintiff's claims are dismissed with prejudice to the extent stated above. Defendant's motion is denied to the extent that plaintiff alleges causes of action based on strict liability failure to warn, negligent failure to warn, and breach of implied warranty.

Of course, plaintiff may not recover twice for the same damages, an issue which may arise later to the extent that her causes of action allege the same resulting harm. See Fasso v. Doerr, 12 N.Y.3d 80, 87 (2009). At this stage, however, we will permit plaintiff's strict liability and negligence failure-to-warn claims as well as her breach of implied warranty claim to proceed to discovery. Cf. Fritz v. White Consol. Indus., Inc., 762 N.Y.S.2d 711, 713 (4th Dep't 2003) (stating that "Supreme Court properly instructed the jury with respect to" the two

causes of action for "strict products liability and breach of implied warranty").

This Memorandum and Order resolves docket entry no. 18. The parties shall appear for a scheduling conference on February 6, 2013, at 2:30 p.m. and shall have conferred before then.

SO ORDERED.

Dated: New York, New York
December 20, 2012

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

Copies of the foregoing Memorandum and Order have been mailed on this date to the following:

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